

treatment records should minimize the costs of the medical aid. However, it is also necessary to consider the cost of the effect achieved and quality price of not only the medical aid itself but the life quality to be created as a result of medical intervention. The latter fact is closely connected with the ethical and moral aspects of the medical aid. It predetermines the obligatoriness and the content of the informed patient's consent to medical intervention that must be a component of the patient's treatment record. Using the results of the pharmacoeconomic investigations and meta-analysis that must cover not only pharmaceutical facilities but also the other diagnostic may solve the described problems and therapeutic services as well. When developing such a system, it is necessary to consider the difficulties that may arise as a result of Russia's current practice to widely use the low-informative methods of diagnostics, low-efficient medicinal preparations, methods of physical therapy, and the unavailability of medical information for the patient.

PPR4

DEVELOPING METHODOLOGICAL STANDARDS IN PHARMACOECONOMIC RESEARCH: AN APPROACH BY A TASK FORCE OF THE AMERICAN COLLEGE OF NEUROPSYCHOPHARMACOLOGY

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Pharmacoeconomic studies are increasing in number along with their use in healthcare decision-making. The methods and analyses used in these studies are often new to clinicians; thus, clinicians may often find it difficult to read, interpret, assess, and use these studies in their own decision-making when comparing products.

OBJECTIVE: In late 1997, the American College of Neuropsychopharmacology (ACNP) convened a task force charged with developing methodological standards that could be used to evaluate CNS-related (e.g., psychiatric, neurologic) pharmacoeconomic studies and be used to rate these studies.

METHODS: The Task Force was comprised of members of the ACNP, non-ACNP scientists, and representatives of the pharmaceutical industry with expertise and interest in pharmacoeconomics. The Task Force first compiled a draft set of rating criteria from existing criteria and other guidelines for pharmacoeconomic studies. Two separate rounds of feasibility tests were conducted during which Task Force members evaluated three pharmacoeconomic studies using the initial and the revised rating scale.

RESULTS: To date, a working rating scale using a 6-point Likert-type responses has been developed which includes 29 aspects of a pharmacoeconomic study over the following seven domains: scope of study, study objectives, sample, methods, definitions, results and discussion, and con-

clusions. The scale is under consideration for use by the ACNP pending further refinement.

CONCLUSIONS: A rating scale has been developed by which to assess pharmacoeconomic studies within a clinical specialty area. Further testing is needed to refine the scale and assess its psychometric properties.

PPR5

ESTIMATING HEALTHCARE COSTS IN THE ABSENCE OF FINANCIAL DATA: A CASE STUDY

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Patient-level healthcare costs are frequently estimated using claims databases or financial records (e.g., hospital bills and institutional cost reports). However, in some healthcare settings, particularly staff model HMOs, this information is absent.

OBJECTIVE: To develop a methodology for estimating costs of healthcare services in the absence of financial data at a staff-model HMO, using the Asthma Outcomes Registry as a case study.

METHODS: The Asthma Outcomes Registry compiled clinical and economic data on individual asthmatic subjects from three US managed care sites. Two sites provided data on utilization and cost of healthcare services derived from health insurance claims. The third site, a staff-model HMO, provided data on service utilization but not cost. We used claims data from the two sites that provided it to impute unit costs of services for treatment of asthma and allergic rhinitis at the third site. Analysis of covariance models were fitted to the logarithm of cost per encounter (or per inpatient day) for patients with such data, and these models were used to assign a cost (retransformed logarithm) to each healthcare encounter at the staff-model HMO. To preserve variation, each encounter's cost was drawn randomly from the distribution (mean and variance) estimated from the other two sites.

RESULTS: Estimated geometric mean costs (logarithms \pm standard error) of outpatient encounters for asthma and allergic rhinitis were \$78.26 ($\4.36 ± 0.014) and \$66.02 ($\4.19 ± 0.032), respectively. Corresponding estimates for emergency visits and inpatient days for asthma were \$208.51 ($\5.34 ± 0.059) and \$820.57 ($\6.71 ± 0.092). Visits for allergy testing were estimated to cost \$25.03 ($\3.22 ± 0.009).

CONCLUSION: Diagnosis-specific unit costs of medical encounters can be imputed in settings where such data are absent using data from comparable settings.

PPR6

COST-EFFECTIVENESS ANALYSIS: A SIMULTANEOUS MARGINAL-EFFECT APPROACH

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OBJECTIVE: The purpose of this study is to develop cost-effectiveness methodology in the context of a simultaneous modeling framework that provides consistent point and interval estimations.

METHODS: A system of cost and effectiveness equations is suggested to model the simultaneity of the underlying cost and effectiveness variables, directly producing a marginal-effect measure of the incremental cost-effectiveness ratio of two competing medical interventions in an evaluative study. Empirical estimation of the simultaneous cost-effectiveness model was conducted using a feasible non-linear least squares estimation method. A simulation analysis of hypothetical data was performed to show the superior performance of the marginal-effect approach, relative to the traditional average-effect approach.

RESULTS: Traditional average-effect approach has two shortcomings. First, it assumes two strong conditions: truly random distributions of all the significant non-intervention variables (both observed and unobserved) across a study's intervention and control groups, and the independence of cost and effectiveness variables. Second, it does not give a confidence interval, an important measure to assess the stochastic nature and robustness of point estimates. In contrast, the simultaneous marginal-effect approach imposed no restrictions on the randomness of the across-group distributions of all the variables. Furthermore, it takes into account the simultaneity of cost and effectiveness functions in estimation. The simulation analysis showed that the marginal-effect approach is significantly more robust, efficient, and unbiased than the average-effect approach in predicting the population true parameters assumed.

CONCLUSION: The simultaneous marginal-effect approach should be chosen over the conventional average-effect approach whenever data allows in assessing the cost-effectiveness of competing interventions in medical decision-making.

PPR7

A FORMAL AUDIT OF 228 PUBLISHED COST-UTILITY ANALYSES

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OBJECTIVE: To understand the evolution and current state of the field, we conducted a formal audit of published cost-utility analyses (CUAs). The objectives were to: 1) develop and test an auditing process for judging the transparency and uniformity of analyses; 2) examine variations in practices in previously published studies; 3) determine whether methods used have been consistent with standard recommendations; and 4) investigate whether analyses have been improving over time.

METHODS: A systematic search of the English-language medical literature identified 228 original CUAs published from 1976 through 1997. Each article was audited independently by two trained readers using a standard data

collection form to determine quality, completeness, and clarity. Data were collected on: 1) background; 2) framing; 3) cost estimation; 4) effectiveness estimation; 5) QALY estimation; 6) reporting of results; 7) discussion; 8) cost/QALY ratios; and 9) readers' subjective assessment of overall quality.

RESULTS: Cost-utility analyses have covered a wide range of diseases and interventions. Most studies have adequately described the comparator intervention (83%), appropriately conducted incremental analysis (86%), discounted both costs and QALYs (72%), and performed sensitivity analysis (89%). Only 52% clearly stated the study perspective; 34% did not disclose the funding source. Methods for estimating costs, effectiveness, and QALYs have varied widely. The quality of published analyses has improved somewhat over time.

CONCLUSION: The results reveal an active and evolving field, but also underscore the need for more consistency and transparency. Concerns about the comparability and credibility of analyses would be allayed with more uniform methods for performance and reporting. Better peer review and independent, third-party audits of the kind used here would likely help in this regard.

USE OF PHARMACOECONOMICS: COUNTRY-SPECIFIC ISSUES

PUP1

PHARMACOECONOMICS IN RUSSIA: FIRST STEPS

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Pharmacoeconomics is one of the most rapidly developing sciences in Western countries. The principles of economic analysis are widely accepted and used. In Russia the situation is almost completely the reverse. The economic impact of new therapies is usually ignored while the use of drugs is dictated by tradition and price. The result is non-evidence-based and non-economically-based clinical practice. The list of best selling drugs in Russia today includes several drugs unheard of in the West. Many drugs which are in high demand have no proven efficacy. Inadequate healthcare financing has put procedure on public purchasing authorities and prescribers to supply the cheapest drugs and generic equivalents sometimes of poor quality. One of the ways to solve the problem is to implement the principles of economic evaluation to policy-making and general practice though the lack of specialists in pharmacoeconomics is an obvious obstacle. Despite several signs of improvement there is still a lot to do. During the last several years a few steps were made to accomplish this goal. They include the creation of Center of Evidence-Based Medicine and Russian branch of ISPOR. Today their main task seems to be dissemination of knowledge through